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General Recommendations on Immu

Recommendations of the Advisory Committee on Immunization

American Academy of Family Physicians (A

Prepared by
William L. Atkinson, M.D.[1]
Larry K. Pickering, M.D.[2]
Benjamin Schwartz, M.D.[3]
Bruce G. Weniger, M.D.[3]
John K. Iskander, M.D.[3]
John C. Watson, M.D.[4]
[1]*Immunization Services Division*
[2]*Office of the Director*
[3]*Epidemiology and Surveillance Division*
National Immunization Program
[4]*Division of Parasitic Diseases*
National Center for Infectious Diseases

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Summary

This report is a revision of General Recommendations on Immunization and updates the 1994 statement by the Advisory Co
General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices [ACI
principal changes include expansion of the discussion of vaccination spacing and timing, recommendations for vaccinations regarding needle-free injection technology, vaccination of children adopted from countries outside the United States, timing screening, expansion of the discussion and tables of contraindications and precautions regarding vaccinations, and addition recommendations are not comprehensive for each vaccine. The most recent ACIP recommendations for each specific vaccin report, ACIP recommendations for each vaccine, and other information regarding immunization can be accessed at CDC's N http://www.cdc.gov/nip (accessed October 11, 2001).

Introduction

This report provides technical guidance regarding common immunization concerns for health-care providers who administer
Vaccine recommendations are based on characteristics of the immunobiologic product, scientific knowledge regarding the pr
epidemiology and burden of diseases (i.e., morbidity, mortality, costs of treatment, and loss of productivity), the safety of va
measures as judged by public health officials and specialists in clinical and preventive medicine.

Benefits and risks are associated with using all immunobiologics. No vaccine is completely safe or 100% effective. Benefits
protection against the consequences of infection for the vaccinated person, as well as overall benefits to society as a whole. E
illness, improved quality of life and productivity, and prevention of death. Societal benefits include creation and maintenanc
diseases, prevention of disease outbreaks, and reduction in health-care--related costs. Vaccination risks range from common,
and life-threatening conditions. Thus, recommendations for immunization practices balance scientific evidence of benefits fo
costs and risks of vaccination programs.

Standards for child and adolescent immunization practices and standards for adult immunization practices (1,2) have been pu

programs and maximizing their benefits. Any person or institution that provides vaccination services should adopt these stan
protect children, adolescents, and adults from vaccine-preventable diseases.

To maximize the benefits of vaccination, this report provides general information regarding immunobiologics and provides p
administration and technique. To minimize risk from vaccine administration, this report delineates situations that warrant pre
These recommendations are intended for use in the United States because vaccine availability and use, as well as epidemiolo
Individual circumstances might warrant deviations from these recommendations. The relative balance of benefits and risks c
For example, because wild poliovirus transmission has been interrupted in the United States since 1979, the only indigenous
that time have been caused by live oral poliovirus vaccine (OPV). In 1997, to reduce the risk for vaccine-associated paralytic
poliovirus vaccine (IPV) was recommended in the United States (*3*). In 1999, to eliminate the risk for VAPP, exclusive use o
in the United States (*4*), and OPV subsequently became unavailable for routine use. However, because of superior ability to i
among close contacts, OPV remains the vaccine of choice for areas where wild poliovirus is still present. Until worldwide er
continued vaccination of the U.S. population against poliovirus will be necessary.

Timing and Spacing of Immunobiologics

General Principles for Vaccine Scheduling

Optimal response to a vaccine depends on multiple factors, including the nature of the vaccine and the age and immune statu
at which vaccines are administered are influenced by age-specific risks for disease, age-specific risks for complications, abili
vaccine, and potential interference with the immune response by passively transferred maternal antibody. Vaccines are recon
at risk for experiencing the disease for whom efficacy and safety have been demonstrated.

Certain products, including inactivated vaccines, toxoids, recombinant subunit and polysaccharide conjugate vaccines, requi
adequate and persisting antibody response. Tetanus and diphtheria toxoids require periodic reinforcement or booster doses to
Unconjugated polysaccharide vaccines do not induce T-cell memory, and booster doses are not expected to produce substant
protein carrier improves the effectiveness of polysaccharide vaccines by inducing T-cell--dependent immunologic function. V
immunity and neutralizing antibodies (e.g., live attenuated virus vaccines) usually can induce prolonged, often lifelong immu
progresses (*5*). Subsequent exposure to infection usually does not lead to viremia but to a rapid anamnestic antibody respons
Approximately 90%--95% of recipients of a single dose of a parenterally administered live vaccine at the recommended age
and yellow fever), develop protective antibody within 2 weeks of the dose. However, because a limited proportion of recipie
dose, a second dose is recommended to provide another opportunity to develop immunity (*6*). The majority of persons who f
a second dose (*7*). Similarly, approximately 20% of persons aged ≥13 years fail to respond to the first dose of varicella vacci
(*8*).

The recommended childhood vaccination schedule is revised annually and is published each January. Recommendations for
less frequently, except for influenza vaccine recommendations, which are published annually. Physicians and other health-ca
following the most up-to-date schedules, which are available from CDC's National Immunization Program website at http://v

Spacing of Multiple Doses of the Same Antigen

Vaccination providers are encouraged to adhere as closely as possible to the recommended childhood immunization schedule
recommended ages and intervals between doses of multidose antigens provide optimal protection or have the best evidence o
recommended intervals between doses are provided in this report (Table 1).

In certain circumstances, administering doses of a multidose vaccine at shorter than the recommended intervals might be nec
schedule and needs to be brought up-to-date as quickly as possible or when international travel is impending. In these situati
intervals between doses shorter than those recommended for routine vaccination. Although the effectiveness of all accelerate
trials, the Advisory Committee on Immunization Practices (ACIP) believes that the immune response when accelerated inter
adequate protection. The accelerated, or minimum, intervals and ages that can be used for scheduling catch-up vaccinations i
should not be administered at intervals less than these minimum intervals or earlier than the minimum age.*

In clinical practice, vaccine doses occasionally are administered at intervals less than the minimum interval or at ages young
close together or at too young an age can lead to a suboptimal immune response. However, administering a dose a limited nu
age is unlikely to have a substantially negative effect on the immune response to that dose. Therefore, ACIP recommends tha
minimum interval or age be counted as valid.† However, because of its unique schedule, this recommendation does not apply
days earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age-appropriat
invalid dose by the recommended minimum interval as provided in this report (Table 1). For example, if *Haemophilus influe*
administered only 2 weeks apart, dose two is invalid and should be repeated. The repeat dose should be administered ≥4 wee
dose would be counted as the second valid dose. Doses administered ≥5 days before the minimum age should be repeated on
≥4 weeks after the invalid dose. For example, if varicella vaccine were administered at age 10 months, the repeat dose would
birthday.

Certain vaccines produce increased rates of local or systemic reactions in certain recipients when administered too frequently
pediatric diphtheria-tetanus toxoid [DT], and tetanus toxoid) (*10,11*). Such reactions are thought to result from the formation
keeping, maintaining patient histories, and adhering to recommended schedules can decrease the incidence of such reactions

Simultaneous Administration

Experimental evidence and extensive clinical experience have strengthened the scientific basis for administering vaccines sir
combined in the same syringe). Simultaneously administering all vaccines for which a person is eligible is critical, including
simultaneous administration increases the probability that a child will be fully immunized at the appropriate age. A study cor
that approximately one third of measles cases among unvaccinated but vaccine-eligible preschool children could have been p
same visit when another vaccine was administered (*12*). Simultaneous administration also is critical when preparing for forei
will return for further doses of vaccine.

Simultaneously administering the most widely used live and inactivated vaccines have produced seroconversion rates and rat
when the vaccines are administered separately (*13--16*). Routinely administering all vaccines simultaneously is recommende
receive them and for whom no specific contraindications exist at the time of the visit. Administering combined MMR vaccin
measles, mumps, and rubella vaccines at different sites. Therefore, no medical basis exists for administering these vaccines s
preferred MMR combined vaccine (*6*). Administering separate antigens would result in a delay in protection for the deferred
vaccines administered on the same day is identical to vaccines administered a month apart (*17*). No evidence exists that OPV
vaccines. OPV can be administered simultaneously or at any interval before or after parenteral live vaccines. No data exist re
typhoid vaccine when administered concurrently or within 30 days of live virus vaccines. In the absence of such data, if typh
delayed because of administration of virus vaccines (*18*).

Simultaneously administering pneumococcal polysaccharide vaccine and inactivated influenza vaccine elicits a satisfactory a
incidence or severity of adverse reactions (*19*). Simultaneously administering pneumococcal polysaccharide vaccine and inac
recommended for all persons for whom both vaccines are indicated.

Hepatitis B vaccine administered with yellow fever vaccine is as safe and immunogenic as when these vaccines are administ
vaccines have been administered safely at the same visit and without reduction of immunogenicity of each of the component

Depending on vaccines administered in the first year of life, children aged 12--15 months can receive ≤7 injections during a
conjugate, diphtheria and tetanus toxoids and acellular pertussis [DTaP], IPV, and hepatitis B vaccines). To help reduce the r
IPV primary series can be completed before the child's first birthday. MMR and varicella vaccines should be administered at
or after the first birthday. The majority of children aged 1 year who have received two (polyribosylribitol phosphate-meningo
three (PRP-tetanus [PRP-T], diphtheria CRM_{197} [CRM, cross-reactive material] protein conjugate [HbOC]) prior doses of Hi
pneumococcal conjugate vaccine have developed protection (*23*,*24*). The third (PRP-OMP) or fourth (PRP-T, HbOC) dose o
pneumococcal conjugate vaccines are critical in boosting antibody titer and ensuring continued protection (*24*--*26*). Howeve
conjugate series can be deferred until ages 15--18 months for children who are likely to return for future visits. The fourth do
ages 15--18 months, but can be administered as early as age 12 months under certain circumstances (*25*). For infants at low r
mother tested negative for hepatitis B surface antigen [HBsAg] at the time of delivery and the child is not of Asian or Pacific
can be completed at any time during ages 6--18 months. Recommended spacing of doses should be maintained (Table 1).

Use of combination vaccines can reduce the number of injections required at an office visit. Licensed combination vaccines
combination are indicated and its other components are not contraindicated. Use of licensed combination vaccines is preferre
component vaccines (*27*). Only combination vaccines approved by the Food and Drug Administration (FDA) should be used
same syringe unless they are specifically approved for mixing by FDA. Only one vaccine (DTaP and PRP-T Hib vaccine, ma
Pasteur]) is FDA-approved for mixing in the same syringe. This vaccine should not be used for primary vaccination in infant
booster after any Hib vaccine.

Nonsimultaneous Administration

Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines. An inactivat
simultaneously or at any time before or after a different inactivated vaccine or live vaccine (Table 2).

The immune response to one live-virus vaccine might be impaired if administered within 30 days of another live-virus vacci
interference between live vaccines. In a study conducted in two U.S. health maintenance organizations, persons who receive
vaccination had an increased risk for varicella vaccine failure (i.e., varicella disease in a vaccinated person) of 2.5-fold comp
before or ≥30 days after MMR (*30*). In contrast, a 1999 study determined that the response to yellow fever vaccine is not affe
administered 1--27 days earlier (*21*). The effect of nonsimultaneously administering rubella, mumps, varicella, and yellow fe

To minimize the potential risk for interference, parenterally administered live vaccines not administered on the same day sho
possible (Table 2). If parenterally administered live vaccines are separated by <4 weeks, the vaccine administered second sho
repeated. The repeat dose should be administered ≥4 weeks after the last, invalid dose. Yellow fever vaccine can be administ
vaccine. Ty21a typhoid vaccine and parenteral live vaccines (i.e., MMR, varicella, yellow fever) can be administered simulta
other, if indicated.

Spacing of Antibody-Containing Products and Vaccines

Live Vaccines

Ty21a typhoid and yellow fever vaccines can be administered at any time before, concurrent with, or after administering any
hepatitis B immune globulin and rabies immune globulin). Blood (e.g., whole blood, packed red blood cells, and plasma) and

immune globulin, hyperimmune globulin, and intravenous immune globulin [IGIV]) can inhibit the immune response to mea
The effect of blood and immune globulin preparations on the response to mumps and varicella vaccines is unknown, but com
antibodies to these viruses. Blood products available in the United States are unlikely to contain a substantial amount of antib
time that interference with parenteral live vaccination (except yellow fever vaccine) can persist after the antibody-containing
specific antibody contained in the product (*31--33*). Therefore, after an antibody-containing product is received, parenteral li
be delayed until the passive antibody has degraded (Table 3). Recommended intervals between receipt of various blood prod
vaccine are listed in this report (Table 4). If a dose of parenteral live-virus vaccine (except yellow fever vaccine) is administe
interval shorter than recommended in this report, the vaccine dose should be repeated unless serologic testing indicates a resp
testing should be performed after the interval indicated for the antibody-containing product (Table 4).
Although passively acquired antibodies can interfere with the response to rubella vaccine, the low dose of anti-Rho(D) globu
been demonstrated to reduce the response to the RA27/3 strain rubella vaccine (*34*). Because of the importance of rubella im
the postpartum vaccination of rubella-susceptible women with rubella or MMR vaccine should not be delayed because of rec
product during the last trimester of pregnancy or at delivery. These women should be vaccinated immediately after delivery a
immunity to rubella and, if necessary, to measles (*6*).
Interference can occur if administering an antibody-containing product becomes necessary after administering MMR, its indi
vaccine virus replication and stimulation of immunity will occur 1--2 weeks after vaccination. Thus, if the interval between a
subsequent administration of an antibody-containing product is <14 days, vaccination should be repeated after the recommen
indicates that antibodies were produced.
A humanized mouse monoclonal antibody product (palivizumab) is available for prevention of respiratory syncytial virus inf
product contains only antibody to respiratory syncytial virus; hence, it will not interfere with immune response to live or inac

Inactivated Vaccines

Antibody-containing products interact less with inactivated vaccines, toxoids, recombinant subunit, and polysaccharide vacci
administering inactivated vaccines and toxoids either simultaneously with or at any interval before or after receipt of an antib
impair development of a protective antibody response (Table 3). The vaccine or toxoid and antibody preparation should be a
recommended dose. Increasing the vaccine dose volume or number of vaccinations is not indicated or recommended.

Interchangeability of Vaccines from Different Manufacturers

Numerous vaccines are available from different ma00048610.htmnufacturers, and these vaccines usually are not identical in
formulation. Manufacturers use different production processes, and their products might contain different concentrations of a
preservatives.
Available data indicate that infants who receive sequential doses of different Hib conjugate, hepatitis B, and hepatitis A vacc
after a complete primary series (*37--40*). All brands of Hib conjugate, hepatitis B,[§] and hepatitis A vaccines are interchangea
brands of Hib conjugate vaccine are administered, a total of three doses is considered adequate for the primary series among
Hib conjugate vaccine can be used for the booster dose at ages 12--18 months.
Data are limited regarding the safety, immunogenicity, and efficacy of using acellular pertussis (as DTaP) vaccines from diff
pertussis series. Available data from one study indicate that, for the first three doses of the DTaP series, one or two doses of
followed by Infanrix® (manufactured by GlaxoSmithKline) for the remaining doses(s) is comparable to three doses of Triped
by antibodies to diphtheria, tetanus, and pertussis toxoid, and filamentous hemagglutinin (*41*). However, in the absence of a
pertussis, the relevance of these immunogenicity data for protection against pertussis is unknown. Whenever feasible, the sa
doses of the vaccination series; however, vaccination providers might not know or have available the type of DTaP vaccine p
situation, any DTaP vaccine should be used to continue or complete the series. Vaccination should not be deferred because th
or is unknown (*25*,*42*).

Lapsed Vaccination Schedule

Vaccination providers are encouraged to administer vaccines as close to the recommended intervals as possible. However, lo
do not reduce final antibody concentrations, although protection might not be attained until the recommended number of dos
vaccination schedule does not require restarting the entire series of a vaccine or toxoid or the addition of extra doses.

Unknown or Uncertain Vaccination Status

Vaccination providers frequently encounter persons who do not have adequate documentation of vaccinations. Providers sho
of vaccination. With the exception of pneumococcal polysaccharide vaccine (*43*), self-reported doses of vaccine without writ
Although vaccinations should not be postponed if records cannot be found, an attempt to locate missing records should be m
and searching for a personally held record. If records cannot be located, these persons should be considered susceptible and s
vaccination schedule. Serologic testing for immunity is an alternative to vaccination for certain antigens (e.g., measles, mum
A, hepatitis B, and poliovirus) (see Vaccination of Internationally Adopted Children).

Contraindications and Precautions

Contraindications and precautions to vaccination dictate circumstances when vaccines will not be administered. The majority

temporary, and the vaccination can be administered later. A contraindication is a condition in a recipient that increases the ris
not be administered when a contraindication is present. For example, administering influenza vaccine to a person with an ana
serious illness in or death of the recipient.
National standards for pediatric immunization practices have been established and include true contraindications and precaut
contraindication applicable to all vaccines is a history of a severe allergic reaction after a prior dose of vaccine or to a vaccin
desensitized). Severely immunocompromised persons should not receive live vaccines. Children who experience an encepha
dose of diphtheria and tetanus toxoids and whole-cell pertussis vaccine (DTP) or DTaP not attributable to another identifiabl
vaccine that contains pertussis. Because of the theoretical risk to the fetus, women known to be pregnant should not receive l
During Pregnancy).
A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise
(e.g., administering measles vaccine to a person with passive immunity to measles from a blood transfusion). Injury could re
reaction to the vaccine than would have otherwise been expected; however, the risk for this happening is less than expected v
circumstances, vaccinations should be deferred when a precaution is present. However, a vaccination might be indicated in th
protection from the vaccine outweighs the risk for an adverse reaction. For example, caution should be exercised in vaccinati
receipt of a prior dose of DTP or DTaP, experienced fever ≥40.5C (105F); had persistent, inconsolable crying for ≥3 hours; c
a seizure ≤3 days after receiving the previous dose of DTP or DTaP. However, administering a pertussis-containing vaccine
increased (e.g., during a pertussis outbreak) (25). The presence of a moderate or severe acute illness with or without a fever i
Other precautions are listed in this report (Table 5).
Physicians and other health-care providers might inappropriately consider certain conditions or circumstances to be true cont
misconception results in missed opportunities to administer recommended vaccines (*44*). Likewise, physicians and other hea
constitutes a true contraindication or precaution and might administer a vaccine when it should be withheld. This practice ca
reaction to the vaccine. Conditions often inappropriately regarded as contraindications to vaccination are listed in this report
and minor upper-respiratory tract illnesses (including otitis media) with or without fever, mild to moderate local reactions to
therapy, and the convalescent phase of an acute illness.
The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of sympto
can be administered to persons with minor acute illness (e.g., diarrhea or mild upper-respiratory tract infection with or witho
children with minor illnesses can seriously impede vaccination efforts (*45--47*). Among persons whose compliance with med
opportunity to provide appropriate vaccinations is critical.
The majority of studies support the safety and efficacy of vaccinating persons who have mild illness (*48--50*). For example, i
illnesses produced measles antibody after vaccination (*51*). Only one limited study has reported a lower rate of seroconversio
vaccine among children with minor, afebrile upper-respiratory tract infections (*52*). Therefore, vaccination should not be del
tract illness or other acute illness with or without fever.
Persons with moderate or severe acute illness should be vaccinated as soon as they have recovered from the acute phase of th
adverse effects of the vaccine on the underlying illness or mistakenly attributing a manifestation of the underlying illness to t
Routine physical examinations and measuring temperatures are not prerequisites for vaccinating infants and children who ap
if the child is ill and then postponing vaccination for those with moderate to severe illness, or proceeding with vaccination if
procedures in childhood immunization programs.
A family history of seizures or other central nervous system disorders is not a contraindication to administration of pertussis
vaccination for infants and children with a history of previous seizures until the child's neurologic status has been assessed is
administered to infants with evolving neurologic conditions until a treatment regimen has been established and the condition

Vaccine Administration

Infection Control and Sterile Technique

Persons administering vaccines should follow necessary precautions to minimize risk for spreading disease. Hands should be
alcohol-based waterless antiseptic hand rub between each patient contact. Gloves are not required when administering vaccin
are likely to come into contact with potentially infectious body fluids or have open lesions on their hands. Syringes and need
disposable to minimize the risk of contamination. A separate needle and syringe should be used for each injection. Changing
injecting it into a recipient is unnecessary. Different vaccines should never be mixed in the same syringe unless specifically l
Disposable needles and syringes should be discarded in labeled, puncture-proof containers to prevent inadvertent needle-stic
injection devices also can reduce the risk for injury and should be used whenever available (see Occupational Safety Regulat

Recommended Routes of Injection and Needle Length

Routes of administration are recommended by the manufacturer for each immunobiologic. Deviation from the recommended
efficacy (*53,54*) or increase local adverse reactions (*55--57*). Injectable immunobiologics should be administered where the l
injury is limited. Vaccines containing adjuvants should be injected into the muscle mass; when administered subcutaneously
induration, skin discoloration, inflammation, and granuloma formation.

Subcutaneous Injections

Subcutaneous injections usually are administered at a 45-degree angle into the thigh of infants aged <12 months and in the u
months. Subcutaneous injections can be administered into the upper-outer triceps area of an infant, if necessary. A 5/8-inch,
subcutaneous tissue.

Intramuscular Injections

Intramuscular injections are administered at a 90-degree angle into the anterolateral aspect of the thigh or the deltoid muscle
for administration of vaccines or toxoids because of the potential risk of injury to the sciatic nerve (*58*). In addition, injection
decreased immunogenicity of hepatitis B and rabies vaccines in adults, presumably because of inadvertent subcutaneous inje
For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seepin
involve underlying nerves and blood vessels or bone (*54,60--62*). Vaccinators should be familiar with the anatomy of the are
individual decision on needle size and site of injection must be made for each person on the basis of age, the volume of the n
and the depth below the muscle surface into which the material is to be injected.

Although certain vaccination specialists advocate aspiration (i.e., the syringe plunger pulled back before injection), no data e
If aspiration results in blood in the needle hub, the needle should be withdrawn and a new site should be selected.

Infants (persons aged <12 months). Among the majority of infants, the anterolateral aspect of the thigh provides the largest
site for injection. For the majority of infants, a 7/8--1-inch, 22--25-gauge needle is sufficient to penetrate muscle in the infan

Toddlers and Older Children (persons aged ≥12 months--18 years). The deltoid muscle can be used if the muscle mass is a
gauge and from 7/8 to 1¼ inches, on the basis of the size of the muscle. For toddlers, the anterolateral thigh can be used, but

Adults (persons aged >18 years). For adults, the deltoid muscle is recommended for routine intramuscular vaccinations. The
needle size is 1--1½ inches and 22--25 gauge.

Intradermal Injections

Intradermal injections are usually administered on the volar surface of the forearm. With the bevel facing upwards, a 3/8--3/4
the epidermis at an angle parallel to the long axis of the forearm. The needle should be inserted so that the entire bevel penet
small bleb. Because of the small amounts of antigen used in intradermal vaccinations, care must be taken not to inject the vac
suboptimal immunologic response.

Multiple Vaccinations

If ≥2 vaccine preparations are administered or if vaccine and an immune globulin preparation are administered simultaneous
different anatomic site. If ≥2 injections must be administered in a single limb, the thigh is usually the preferred site because
be sufficiently separated (i.e., ≥1 inch) so that any local reactions can be differentiated (*55,63*). For older children and adults
intramuscular injections, if necessary. The location of each injection should documented in the person's medical record.

Jet Injection

Jet injectors (JIs) are needle-free devices that drive liquid medication through a nozzle orifice, creating a narrow stream unde
drug or vaccine into intradermal, subcutaneous, or intramuscular tissues (*64,65*). Increasing attention to JI technology as an a
resulted from recent efforts to reduce the frequency of needle-stick injuries to health-care workers (*66*) and to overcome the i
and syringes in economically developing countries (*67--69*). JIs have been reported safe and effective in administering differ
bacterial diseases (*69*). The immune responses generated are usually equivalent to, and occasionally greater than, those induc
or injury (e.g., redness, induration, pain, blood, and ecchymosis at the injection site) can be more frequent for vaccines deliv
(*65,69*).

Certain JIs were developed for situations in which substantial numbers of persons must be vaccinated rapidly, but personnel
conventional needle injection. Such high-workload devices vaccinate consecutive patients from the same nozzle orifice, fluic
automatically from attached vials containing ≤50 doses each. Since the 1950s, these devices have been used extensively amo
campaigns for disease control and eradication (*64*). An outbreak of hepatitis B among patients receiving injections from a mu
and subsequent laboratory, field, and animal studies demonstrated that such devices could become contaminated with blood
No U.S.-licensed, high-workload vaccination devices of unquestioned safety are available to vaccination programs. Efforts a
new high-workload JIs using disposable-cartridge technology that avoids reuse of any unsterilized components having conta
blood. Until such devices become licensed and available, the use of existing multiple-use--nozzle JIs should be limited. Use
bloodborne disease transmission is outweighed by the benefits of rapid vaccination with limited personnel in responding to s
bioterrorism event), and by any competing risks of iatrogenic or occupational infections resulting from conventional needles
multiple-use--nozzle JIs, health-care workers should consult with local, state, national, or international health agencies or org
In the 1990s, a new generation of low-workload JIs were introduced with disposable cartridges serving as dose chambers and
cartridge for each patient and other correct use, these devices avoid the safety concerns described previously for multiple-use
with their labeling for intradermal, subcutaneous, or intramuscular administration.

Methods for Alleviating Discomfort and Pain Associated with Vaccination

Comfort measures and distraction techniques (e.g., playing music or pretending to blow away the pain) might help children c
vaccination. Pretreatment (30-60 minutes before injection) with 5% topical lidocaine-prilocaine emulsion (EMLA® cream or
decrease the pain of vaccination among infants by causing superficial anesthesia (*74,75*). Preliminary evidence indicates that

response to MMR (*76*). Topical lidocaine-prilocaine emulsion should not be used on infants aged <12 months who are receiv
agents because of the possible development of methemoglobinemia (*77*). Acetaminophen has been used among children to re
vaccination (*78*). However, acetaminophen can cause formation of methemoglobin and, thus, might interact with lidocaine-p
Ibuprofen or other nonaspirin analgesic can be used, if necessary. Use of a topical refrigerant (vapocoolant) spray can reduce
and can be as effective as lidocaine-prilocaine cream (*79*). Administering sweet-tasting fluid orally immediately before injec
among certain infants.

Nonstandard Vaccination Practices

Recommendations regarding route, site, and dosage of immunobiologics are derived from data from clinical trials, from prac
considerations. ACIP strongly discourages variations from the recommended route, site, volume, or number of doses of any
Variation from the recommended route and site can result in inadequate protection. The immunogenicity of hepatitis B vacci
the gluteal rather than the deltoid site is used for administration (*53,59*). Hepatitis B vaccine administered intradermally can
of hepatitis B surface antibody than when administered by the deltoid intramuscular route (*80,81*). Doses of rabies vaccine ad
counted as valid doses and should be repeated. Hepatitis B vaccine administered by any route or site other than intramuscula
should not be counted as valid and should be repeated, unless serologic testing indicates that an adequate response has been a
Live attenuated parenteral vaccines (e.g., MMR, varicella, or yellow fever) and certain inactivated vaccines (e.g., IPV, pneur
recommended by the manufacturers to be administered by subcutaneous injection. Pneumococcal polysaccharide and IPV ar
subcutaneous administration. Response to these vaccines probably will not be affected if the vaccines are administered by th
Repeating doses of vaccine administered by the intramuscular route rather than by the subcutaneous route is unnecessary.
Administering volumes smaller than those recommended (e.g., split doses) can result in inadequate protection. Using larger t
because of excessive local or systemic concentrations of antigens or other vaccine constituents. Using multiple reduced dose
using smaller divided doses is not endorsed or recommended. Any vaccination using less than the standard dose should not b
according to age, unless serologic testing indicates that an adequate response has been achieved.

Preventing Adverse Reactions

Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an untoward effect that occurs
vaccine's primary purpose of producing immunity. Adverse reactions also are called *vaccine side effects*.
All vaccines might cause adverse reactions (82). Vaccine adverse reactions are classified by three general categories: local, s
the least severe and most frequent. Systemic reactions (e.g., fever) occur less frequently than local reactions. Serious allergic
and least frequent. Severe adverse reactions are rare.
The key to preventing the majority of serious adverse reactions is screening. Every person who administers vaccines should
precautions to the vaccine before it is administered (Table 5). Standardized screening questionnaires have been developed an
programs and other sources (e.g., the Immunization Action Coalition at http://www.immunize.org [accessed October 31, 200
Severe allergic reactions after vaccination are rare. However, all physicians and other health-care providers who administer v
emergency management of a person who experiences an anaphylactic reaction. All vaccine providers should be familiar with
cardiopulmonary resuscitation.
Syncope (vasovagal or vasodepressor reaction) can occur after vaccination, most commonly among adolescents and young a
reports to the Vaccine Adverse Event Reporting system were coded as syncope. Forty percent of these episodes were reporte
unpublished data, 2001). Approximately 12% of reported syncopal episodes resulted in hospitalization because of injury or n
fractures and cerebral bleeding, have been reported to result from syncopal episodes after vaccination. A published review of
syncopal episodes occurred ≤5 minutes after vaccination, and 89% occurred within 15 minutes after vaccination (*83*). Althou
allergic reactions are rare, certain vaccination specialists recommend that persons be observed for 15--20 minutes after being
patients should be observed until the symptoms resolve.

Managing Acute Vaccine Reactions

Although rare after vaccination, the immediate onset and life-threatening nature of an anaphylactic reaction require that pers
capable of providing initial care for suspected anaphylaxis. Epinephrine and equipment for maintaining an airway should be
Anaphylaxis usually begins within minutes of vaccine administration. Rapidly recognizing and initiating treatment are requir
cardiovascular collapse. If flushing, facial edema, urticaria, itching, swelling of the mouth or throat, wheezing, difficulty brea
patient should be placed in a recumbent position with the legs elevated. Aqueous epinephrine (1:1000) should be administere
(*84*). A dose of diphenhydramine hydrochloride might shorten the reaction, but it will have little immediate effect. Maintena
be necessary. Arrangements should be made for immediate transfer to an emergency facility for further evaluation and treatm

Occupational Safety Regulations

Bloodborne diseases (e.g., hepatitis B and C and human immunodeficiency virus [HIV]) are occupational hazards for health-
incidence of needle-stick injuries among health-care workers and the consequent risk for bloodborne diseases acquired from
Act was signed into law. The act directed the Occupational Safety and Health Administration (OSHA) to strengthen its existi
standards were revised and became effective in April 2001 (*66*). These federal regulations require that safer injection devices
injectors) be used for parenteral vaccination in all clinical settings when such devices are appropriate, commercially availabl

purpose. The rules also require that records be kept documenting the incidence of injuries caused by medical sharps (except i
nonmanagerial employees be involved in the evaluation and selection of safer devices to be procured.
Needle-shielding or needle-free devices that might satisfy the occupational safety regulations for administering parenteral inj
listed at multiple websites (*69,85--87*).[¶] Additional information regarding implementation and enforcement of these regulatio
http://www.osha-slc.gov/needlesticks (accessed October 31, 2001).

Storage and Handling of Immunobiologics

Failure to adhere to recommended specifications for storage and handling of immunobiologics can reduce potency, resulting
recipient. Recommendations included in a product's package insert, including reconstitution of the vaccine, should be follow
responsibility of all parties from the time the vaccine is manufactured until administration. All vaccines should be inspected
ensure that the cold chain has been maintained. Vaccines should continue to be stored at recommended temperatures immedi
varicella, and yellow fever) are sensitive to increased temperature. All other vaccines are sensitive to freezing. Mishandled v
vaccine. When in doubt regarding the appropriate handling of a vaccine, vaccination providers should contact the manufactu
inactivated vaccines and toxoids that have been exposed to freezing temperatures) or that are beyond their expiration date sh
expired vaccines are administered inadvertently, they should not be counted as valid doses and should be repeated, unless se
Live attenuated virus vaccines should be administered promptly after reconstitution. Varicella vaccine must be administered
vaccine must be used ≤1 hour after reconstitution. MMR vaccine must be administered ≤8 hours after reconstitution. If not a
after reconstitution, the vaccine must be discarded.
The majority of vaccines have a similar appearance after being drawn into a syringe. Instances in which the wrong vaccine ir
the practice of prefilling syringes or drawing doses of a vaccine into multiple syringes before their immediate need. ACIP dis
syringes because of the potential for such administration errors. To prevent errors, vaccine doses should not be drawn into a
In certain circumstances where a single vaccine type is being used (e.g., in advance of a community influenza vaccination ca
immediate use can be considered. Care should be taken to ensure that the cold chain is maintained until the vaccine is admini
vaccine, lot number, and date of filling must be carefully labeled on each syringe, and the doses should be administered as sc
Certain vaccines are distributed in multidose vials. When opened, the remaining doses from partially used multidose vials ca
on the vial or vaccine packaging, provided that the vial has been stored correctly and that the vaccine is not visibly contamin

Special Situations

Concurrently Administering Antimicrobial Agents and Vaccines

With limited exceptions, using an antibiotic is not a contraindication to vaccination. Antimicrobial agents have no effect on t
live oral Ty21a typhoid vaccine, and have no effect on inactivated, recombinant subunit, or polysaccharide vaccines or toxoi
administered to persons receiving antimicrobial agents until ≥24 hours after any antibiotic dose (*18*).
Antiviral drugs used for treatment or prophylaxis of influenza virus infections have no effect on the response to inactivated ir
against herpesviruses (e.g., acyclovir or valacyclovir) might reduce the efficacy of live attenuated varicella vaccine. These dr
administration of varicella vaccine, if possible.
The antimalarial drug mefloquine (Lariam® [manufactured by Roche Laboratories, Inc.]) could affect the immune response t
simultaneously (*89,90*). To minimize this effect, administering Ty21a typhoid vaccine ≥24 hours before or after a dose of me

Tuberculosis Screening and Skin Test Reactivity

Measles illness, severe acute or chronic infections, HIV infection, and malnutrition can create an anergic state during which t
protein derivative [*PPD*] skin test) might give a false negative reaction (*91--93*). Although any live attenuated measles vacci
degree of suppression is probably less than that occurring from acute infection from wild measles virus. Although routine PP
recommended, PPD screening is sometimes needed at the same time as administering a measles-containing vaccine (e.g., for
health reasons), and the following options should be considered:

- PPD and measles-containing vaccine can be administered at the same visit (preferred option). Simultaneously admi
  does not interfere with reading the PPD result at 48--72 hours and ensures that the person has received measles vacc
- If the measles-containing vaccine has been administered recently, PPD screening should be delayed ≥4 weeks after
  remove the concern of any theoretical but transient suppression of PPD reactivity from the vaccine.
- PPD screening can be performed and read before administering the measles-containing vaccine. This option is the le
  measles-containing vaccine.

No data exist for the potential degree of PPD suppression that might be associated with other parenteral live attenuated virus
Nevertheless, in the absence of data, following guidelines for measles-containing vaccine when scheduling PPD screening ar
virus vaccines is prudent. If a risk exists that the opportunity to vaccinate might be missed, vaccination should not be delayed
Mucosally administered live attenuated virus vaccines (e.g., OPV and intranasally administered influenza vaccine) are unlike
been reported that inactivated vaccines, polysaccharide vaccines, recombinant, or subunit vaccines, or toxoids interfere with
PPD reactivity in the absence of tuberculosis disease is not a contraindication to administration of any vaccine, including par
Tuberculosis disease is not a contraindication to vaccination, unless the person is moderately or severely ill. Although no stu

persons with untreated tuberculosis, a theoretical basis exists for concern that measles vaccine might exacerbate tuberculosis
persons with untreated active tuberculosis, initiating antituberculosis therapy is advisable (*6*). Ruling out concurrent immuno
HIV infection) before administering live attenuated vaccines is also prudent.

Severe Allergy to Vaccine Components

Vaccine components can cause allergic reactions among certain recipients. These reactions can be local or systemic and can
anaphylactic-like responses (e.g., generalized urticaria or hives, wheezing, swelling of the mouth and throat, difficulty breath
might be caused by the vaccine antigen, residual animal protein, antimicrobial agents, preservatives, stabilizers, or other vacc
vaccine components, their use, and the vaccines that contain each component has been published (*95*) and is also available fr
website at http://www.cdc.gov/nip (accessed October 31, 2001).

The most common animal protein allergen is egg protein, which is found in vaccines prepared by using embryonated chicken
Ordinarily, persons who are able to eat eggs or egg products safely can receive these vaccines; persons with histories of anap
egg proteins should not be administered these vaccines. Asking persons if they can eat eggs without adverse effects is a reasc
allergic reactions from receiving yellow fever and influenza vaccines. A regimen for administering influenza vaccine to childr
has been developed (*96*).

Measles and mumps vaccine viruses are grown in chick embryo fibroblast tissue culture. Persons with a serious egg allergy c
vaccines without skin testing or desensitization to egg protein (*6*). Rubella and varicella vaccines are grown in human diploid
persons with histories of severe allergy to eggs or egg proteins. The rare serious allergic reaction after measles or mumps vac
by egg antigens, but to other components of the vaccine (e.g., gelatin) (*97--100*). MMR, its component vaccines, and other va
Extreme caution should be exercised when administering vaccines that contain gelatin to persons who have a history of an ar
containing products. Before administering gelatin-containing vaccines to such persons, skin testing for sensitivity to gelatin c
for this approach have been published.

Certain vaccines contain trace amounts of antibiotics or other preservatives (e.g., neomycin or thimerosal) to which patients
provided in the vaccine package insert should be reviewed carefully before deciding if the rare patient with such allergies sho
contains penicillin or penicillin derivatives.

Certain vaccines contain trace amounts of neomycin. Persons who have experienced anaphylactic reactions to neomycin shou
neomycin allergy is a contact dermatitis, a manifestation of a delayed type (cell-mediated) immune response, rather than ana
reactions to neomycin is not a contraindication for administration of these vaccines.

Thimerosal is an organic mercurial compound in use since the 1930s and added to certain immunobiologic products as a pres
Public Health Service and the American Academy of Pediatrics (AAP) in 1999 (*103*) and agreed to by the American Acaden
established the goal of removing thimerosal as soon as possible from vaccines routinely recommended for infants. Although
levels of thimerosal in vaccines and the risk was only theoretical (*104*), this goal was established as a precautionary measure
The public is concerned about the health effects of mercury exposure of any type, and the elimination of mercury from vacci
infant's total exposure to mercury in a world where other environmental sources of exposure are more difficult or impossible
vaccines routinely recommended for children have been manufactured without thimerosal as a preservative and contain eithe
as a preservative is present in certain other vaccines (e.g., Td, DT, one of two adult hepatitis B vaccines, and influenza vacci
of influenza vaccine was licensed by FDA in September 2001.

Receiving thimerosal-containing vaccines has been believed to lead to induction of allergy. However, limited scientific basis
thimerosal usually consists of local delayed type hypersensitivity reactions (*105--107*). Thimerosal elicits positive delayed ty
persons tested, but these tests have limited or no clinical relevance (*108,109*). The majority of patients do not experience reac
of vaccines even when patch or intradermal tests for thimerosal indicate hypersensitivity (*109*). A localized or delayed type h
contraindication to receipt of a vaccine that contains thimerosal.

Latex Allergy

Latex is liquid sap from the commercial rubber tree. Latex contains naturally occurring impurities (e.g., plant proteins and pe
allergic reactions. Latex is processed to form natural rubber latex and dry natural rubber. Dry natural rubber and natural rubb
as latex but in lesser amounts. Natural rubber latex is used to produce medical gloves, catheters, and other products. Dry natu
stoppers, and injection ports on intravascular tubing. Synthetic rubber and synthetic latex also are used in medical gloves, sy
and synthetic latex do not contain natural rubber or natural latex, and therefore, do not contain the impurities linked to allergi

The most common type of latex sensitivity is contact-type (type 4) allergy, usually as a result of prolonged contact with latex
procedure--associated latex allergies among patients with diabetes have been described (*111--113*). Allergic reactions (includ
rare. Only one report of an allergic reaction after administering hepatitis B vaccine in a patient with known severe allergy (ar

If a person reports a severe (anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain natural rubber s
vaccination outweighs the risk of an allergic reaction to the vaccine. For latex allergies other than anaphylactic allergies (e.g.
vaccines supplied in vials or syringes that contain dry natural rubber or natural rubber latex can be administered.

Vaccination of Premature Infants

In the majority of cases, infants born prematurely, regardless of birth weight, should be vaccinated at the same chronological

precautions as full-term infants and children. Birth weight and size are not factors in deciding whether to postpone routine va
(*115--117*), except for hepatitis B vaccine. The full recommended dose of each vaccine should be used. Divided or reduced d
Studies demonstrate that decreased seroconversion rates might occur among certain premature infants with low birth weights
hepatitis B vaccine at birth (*119*). However, by chronological age 1 month, all premature infants, regardless of initial birth w
adequately as older and larger infants (*120--122*). A premature infant born to HBsAg-positive mothers and mothers with unk
immunoprophylaxis with hepatitis B vaccine and hepatitis B immunoglobulin (HBIG) ≤12 hours after birth. If these infants v
dose should not be counted towards completion of the hepatitis B vaccine series, and three additional doses of hepatitis B vac
infant is age 1 month. The optimal timing of the first dose of hepatitis B vaccine for premature infants of HBsAg-negative m
not been determined. However, these infants can receive the first dose of the hepatitis B vaccine series at chronological age 1
hospital before chronological age 1 month can also be administered hepatitis B vaccine at discharge, if they are medically sta

Breast-Feeding and Vaccination

Neither inactivated nor live vaccines administered to a lactating woman affect the safety of breast-feeding for mothers or infa
immunization and is not a contraindication for any vaccine. Limited data indicate that breast-feeding can enhance the respon
infants should be vaccinated according to routine recommended schedules (*124--126*).
Although live vaccines multiply within the mother's body, the majority have not been demonstrated to be excreted in human
excreted in human milk, the virus usually does not infect the infant. If infection does occur, it is well-tolerated because the vi
recombinant, subunit, polysaccharide, conjugate vaccines and toxoids pose no risk for mothers who are breast-feeding or for

Vaccination During Pregnancy

Risk to a developing fetus from vaccination of the mother during pregnancy is primarily theoretical. No evidence exists of ris
inactivated virus or bacterial vaccines or toxoids (*128,129*). Benefits of vaccinating pregnant women usually outweigh poten
is high, when infection would pose a risk to the mother or fetus, and when the vaccine is unlikely to cause harm.
Td toxoid is indicated routinely for pregnant women. Previously vaccinated pregnant women who have not received a Td vac
booster dose. Pregnant women who are not immunized or only partially immunized against tetanus should complete the prim
seeks prenatal care and the required interval between doses, one or two doses of Td can be administered before delivery. Wo
have not completed the recommended three-dose series during pregnancy, should receive follow-up after delivery to ensure t
Women in the second and third trimesters of pregnancy have been demonstrated to be at increased risk for hospitalization fro
vaccination is recommended for healthy women who will be beyond the first trimester of pregnancy (i.e., ≥14 weeks of gesta
-March in the United States) (*88*). Women who have medical conditions that increase their risk for complications of influenz
season, regardless of the stage of pregnancy.
IPV can be administered to pregnant women who are at risk for exposure to wild-type poliovirus infection (*4*). Hepatitis B va
risk for hepatitis B virus infection (*132*). Hepatitis A, pneumococcal polysaccharide, and meningococcal polysaccharide vacc
increased risk for those infections (*43*,*133*,*134*).
Pregnant women who must travel to areas where the risk for yellow fever is high should receive yellow fever vaccine, becau
substantially outweighed by the risk for yellow fever infection (*22*,*135*). Pregnancy is a contraindication for measles, mumps
theoretical concern, no cases of congenital rubella or varicella syndrome or abnormalities attributable to fetal infection have
women who received rubella or varicella vaccines during pregnancy (*6*,*136*). Because of the importance of protecting women
practices in any immunization program include asking women if they are pregnant or intend to become pregnant in the next 4
they are pregnant, explaining the potential risk for the fetus to women who state that they are not pregnant, and counseling w
during the 4 weeks after MMR vaccination (*6*,*35*,*137*). Routine pregnancy testing of women of childbearing age before admi
(*6*). If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after MMR or varicella vacc
theoretical basis of concern for the fetus; however, MMR or varicella vaccination during pregnancy should not ordinarily be
Persons who receive MMR vaccine do not transmit the vaccine viruses to contacts (*6*). Transmission of varicella vaccine viru
vaccines should be administered when indicated to the children and other household contacts of pregnant women (*6*,*8*).
All pregnant women should be evaluated for immunity to rubella and be tested for the presence of HBsAg (*6*,*35*,*132*). Wome
immediately after delivery. A woman known to be HBsAg-positive should be followed carefully to ensure that the infant rec
series ≤12 hours after birth and that the infant completes the recommended hepatitis B vaccine series (*132*). No known risk e
pregnant women with immune globulin preparations.

Vaccination of Internationally Adopted Children

The ability of a clinician to determine that a person is protected on the basis of their country of origin and their records alone
should receive vaccines according to recommended schedules for children in the United States. Only written documentation
vaccination. Written records are more likely to predict protection if the vaccines, dates of administration, intervals between d
immunization are comparable to the current U.S. recommendations. Although vaccines with inadequate potency have been p
of vaccines used worldwide are produced with adequate quality control standards and are potent.
The number of American families adopting children from outside the United States has increased substantially in recent year
have immunization schedules that differ from the recommended childhood immunization schedule in the United States. Diffe

those used in other countries include the vaccines administered, the recommended ages of administration, and the number an
Data are inconclusive regarding the extent to which an internationally adopted child's immunization record reflects the child'
administration of MMR vaccine when only single-antigen measles vaccine was administered. A study of children adopted fr
Eastern Europe determined that only 39% (range: 17%--88% by country) of children with documentation of >3 doses of DTI
diphtheria and tetanus antitoxin (*142*). However, antibody testing was performed by using a hemagglutination assay, which t
directly be compared with antibody concentration (*143*). Another study measured antibody to diphtheria and tetanus toxins a
received ≥2 doses of DTP. The majority of the children were from Russia, Eastern Europe, and Asian countries, and 78% ha
Overall, 94% had evidence of protection against diphtheria (EIA > 0.1 IU/mL). A total of 84% had protection against tetanus
> 0.5 IU/mL). Among children without protective tetanus antitoxin concentration, all except one had records of ≥3 doses of
concentrations were categorized as indeterminate (ELISA = 0.05--0.49 IU/mL) (*144*). Reasons for the discrepant findings in
laboratory methodologies; the study using a hemagglutination assay might have underestimated the number of children who
standardized methodologies are needed. Data are likely to remain limited for countries other than the People's Republic of C
limited number of adoptees from other countries.

Physicians and other health-care providers can follow one of multiple approaches if a question exists regarding whether vacc
were immunogenic. Repeating the vaccinations is an acceptable option. Doing so is usually safe and avoids the need to obtai
unnecessary injections is desired, judicious use of serologic testing might be helpful in determining which immunizations are
possible approaches to evaluation and revaccination for each vaccine recommended universally for children in the United St

MMR Vaccine

The simplest approach to resolving concerns regarding MMR immunization among internationally adopted children is to rev
depending on the child's age. Serious adverse events after MMR vaccinations are rare (*6*). No evidence indicates that admini
adverse reactions among persons who are already immune to measles, mumps, or rubella as a result of previous vaccination
vaccine administered before the first birthday should not be counted as part of the series (*6*). Alternatively, serologic testing
viruses indicated on the vaccination record can be considered. Serologic testing is widely available for measles and rubella Ig
receipt of monovalent measles or measles-rubella vaccine at age ≥1 year and who has protective antibody against measles an
age-appropriate to ensure protection against mumps (and rubella if measles vaccine alone had been used). If a child whose re
has a protective concentration of antibody to measles, no additional vaccination is needed unless required for school entry.

Hib Vaccine

Serologic correlates of protection for children vaccinated >2 months previously might be difficult to interpret. Because the n
decreases with age and adverse events are rare (*24*), age-appropriate vaccination should be provided. Hib vaccination is not r
years.

Hepatitis B Vaccine

Serologic testing for HBsAg is recommended for international adoptees, and children determined to be HBsAg-positive shou
disease. Household members of HBsAg-positive children should be vaccinated. A child whose records indicate receipt of ≥3
and additional doses are not needed if ≥1 doses were administered at age ≥6 months. Children who received their last hepatit
receive an additional dose at age ≥6 months. Those who have received <3 doses should complete the series at the recommen

Poliovirus Vaccine

The simplest approach is to revaccinate internationally adopted children with IPV according to the U.S. schedule. Adverse ev
appropriately vaccinated with three doses of OPV in economically developing countries might have suboptimal seroconversi
Serologic testing for neutralizing antibody to poliovirus types 1, 2, and 3 can be obtained commercially and at certain state h
protective titers against all three types do not need revaccination and should complete the schedule as age-appropriate. Alter
dose of IPV is excellent among children who previously received OPV (*3*), a single dose of IPV can be administered initially

DTaP Vaccine

Vaccination providers can revaccinate a child with DTaP vaccine without regard to recorded doses; however, one concern re
increased rates of local adverse reactions after the fourth and fifth doses of DTP or DTaP (*42*). If a revaccination approach is
serologic testing for specific IgG antibody to tetanus and diphtheria toxins can be measured before administering additional
further doses are unnecessary and subsequent vaccination should occur as age-appropriate. No established serologic correlate
For a child whose record indicates receipt of ≥3 doses of DTP or DTaP, serologic testing for specific IgG antibody to both di
is a reasonable approach. If a protective concentration is present, recorded doses can be considered valid, and the vaccinatior
Indeterminate antibody concentration might indicate immunologic memory but antibody waning; serology can be repeated a
wishes to avoid revaccination with a complete series.

Alternately, for a child whose records indicate receipt of ≥3 doses, a single booster dose can be administered, followed by se
antibody to both diphtheria and tetanus toxins. If a protective concentration is obtained, the recorded doses can be considered
age-appropriate. Children with indeterminate concentration after a booster dose should be revaccinated with a complete serie

Varicella Vaccine

Varicella vaccine is not administered in the majority of countries. A child who lacks a reliable medical history regarding pric

appropriate (*8*).

Pneumococcal Vaccines

Pneumococcal conjugate and pneumococcal polysaccharide vaccines are not administered in the majority of countries and sh indicated by the presence of underlying medical conditions (*26*,*43*).

Altered Immunocompetence

ACIP's statement regarding vaccinating immunocompromised persons summarizes recommendations regarding the efficacy, globulin preparations for immunocompromised persons (*145*). ACIP statements regarding individual vaccines or immune glo those concerns.

Severe immunosuppression can be the result of congenital immunodeficiency, HIV infection, leukemia, lymphoma, generali antimetabolites, radiation, or a high dose, prolonged course of corticosteroids. The degree to which a person is immunocomp Severe complications have followed vaccination with live-virus vaccines and live bacterial vaccines among immunocompron not receive live vaccines except in certain circumstances that are noted in the following paragraphs. MMR vaccine viruses ar varicella vaccine virus is rare (*6*,*138*). MMR and varicella vaccines should be administered to susceptible household and oth when indicated.

Persons with HIV infection are at increased risk for severe complications if infected with measles. No severe or unusual adv vaccination among HIV-infected persons who did not have evidence of severe immunosuppression (*154--157*). As a result, M infected persons who do not have evidence of severe immunosuppression[††] and for whom measles vaccination would otherw Children with HIV infection are at increased risk for complications of primary varicella and for herpes zoster, compared with data among asymptomatic or mildly symptomatic HIV-infected children (CDC class N1 or A1, age-specific $CD4^+$ lymphocy vaccine is immunogenic, effective, and safe (*138*,*159*). Varicella vaccine should be considered for asymptomatic or mildly sy N1 or A1 with age-specific $CD4^+$ T lymphocyte percentages of ≥25%. Eligible children should receive two doses of varicella (*138*).

HIV-infected persons who are receiving regular doses of IGIV might not respond to varicella vaccine or MMR or its individ presence of passively acquired antibody. However, because of the potential benefit, measles vaccination should be considere scheduled dose of IGIV (if not otherwise contraindicated), although an optimal immune response is unlikely to occur. Unless antibodies have been produced, vaccination should be repeated (if not otherwise contraindicated) after the recommended inte be considered for persons on maintenance IGIV therapy who are exposed to measles ≥3 weeks after administering a standard Persons with cellular immunodeficiency should not receive varicella vaccine. However, ACIP recommends that persons with hypogammaglobulinemia or dysgammaglobulinemia) should be vaccinated (*138*,*160*).

Inactivated, recombinant, subunit, polysaccharide, and conjugate vaccines and toxoids can be administered to all immunocor vaccines might be suboptimal. If indicated, all inactivated vaccines are recommended for immunocompromised persons in us pneumococcal, meningococcal, and Hib vaccines are recommended specifically for certain groups of immunocompromised p anatomic asplenia (*145*,*161*).

Except for influenza vaccine, which should be administered annually (*88*), vaccination during chemotherapy or radiation the is suboptimal. Patients vaccinated while receiving immunosuppressive therapy or in the 2 weeks before starting therapy shou revaccinated ≥3 months after therapy is discontinued. Patients with leukemia in remission whose chemotherapy has been ter vaccines.

Corticosteroids

The exact amount of systemically absorbed corticosteroids and the duration of administration needed to suppress the immun person are not well-defined. The majority of experts agree that corticosteroid therapy usually is not a contraindication to adm (i.e., <2 weeks); a low to moderate dose; long-term, alternate-day treatment with short-acting preparations; maintenance phy administered topically (skin or eyes) or by intra-articular, bursal, or tendon injection (*145*). Although of theoretical concern, live vaccines has been reported among persons receiving corticosteroid therapy by aerosol, and such therapy is not a reason t effects of steroid treatment vary, but the majority of clinicians consider a dose equivalent to either ≥2 mg/kg of body weight equivalent for children who weigh >10 kg, when administered for ≥2 weeks as sufficiently immunosuppressive to raise conc virus vaccines (*84*,*145*). Corticosteroids used in greater than physiologic doses also can reduce the immune response to vacci after discontinuation of therapy before administering a live-virus vaccine to patients who have received high systemically ab

Vaccination of Hematopoietic Stem Cell Transplant Recipients

Hematopoietic stem cell transplant (HSCT) is the infusion of hematopoietic stem cells from a donor into a patient who has re which are usually bone marrow ablative. HSCT is used to treat a variety of neoplastic diseases, hematologic disorders, immu deficiencies, and autoimmune disorders. HSCT recipients can receive either their own cells (i.e., autologous HSCT) or cells f (i.e., allogeneic HSCT). The source of the transplanted stem cells can be from either a donor's bone marrow or peripheral blo newborn infant (*162*).

Antibody titers to vaccine-preventable diseases (e.g., tetanus, poliovirus, measles, mumps, rubella, and encapsulated bacteria autologous HSCT if the recipient is not revaccinated (*163--167*). HSCT recipients are at increased risk for certain vaccine-pr

encapsulated bacteria (i.e., pneumococcal and Hib infections). As a result, HSCT recipients should be routinely revaccinated transplanted stem cells. Revaccination with inactivated, recombinant, subunit, polysaccharide, and Hib vaccines should begi this recommendation is for influenza vaccine, which should be administered at ≥6 months after HSCT and annually for the li should be administered 24 months after transplantation if the HSCT recipient is presumed to be immunocompetent. Varicell vaccines are not recommended for HSCT recipients because of insufficient experience using these vaccines among HSCT re contacts of HSCT recipients and health-care workers who care for HSCT recipients, should be appropriately vaccinated, incl Additional details of vaccination of HSCT recipients and their contacts can be found in a specific CDC report on this topic (

Vaccinating Persons with Bleeding Disorders and Persons Receiving Anticoagulant Therapy

Persons with bleeding disorders (e.g., hemophilia) and persons receiving anticoagulant therapy have an increased risk for acc general population of acquiring other vaccine-preventable diseases. However, because of the risk for hematoma formation af avoided among persons with bleeding disorders by using the subcutaneous or intradermal routes for vaccines that are admini Hepatitis B vaccine administered intramuscularly to 153 persons with hemophilia by using a 23-gauge needle, followed by s resulted in a 4% bruising rate with no patients requiring factor supplementation (*168*). Whether antigens that produce more l equally low rate of bruising is unknown.

When hepatitis B or any other intramuscular vaccine is indicated for a patient with a bleeding disorder or a person receiving administered intramuscularly if, in the opinion of a physician familiar with the patient's bleeding risk, the vaccine can be adn the patient receives antihemophilia or similar therapy, intramuscular vaccinations can be scheduled shortly after such therapy should be used for the vaccination and firm pressure applied to the site, without rubbing, for ≥2 minutes. The patient or fami hematoma from the injection.

Vaccination Records

Consent to Vaccinate

The National Childhood Vaccine Injury Act of 1986 (42 U.S.C. § 300aa-26) requires that all health-care providers in the Uni the act[§§] must provide a copy of the relevant, current edition of the vaccine information materials that have been produced by vaccine. The vaccine information material must be provided to the parent or legal representative of any child or to any adult provider intends to administer the vaccine. The Act does not require that a signature be obtained, but documentation of conse local authorities.

Provider Records

Documentation of patient vaccinations helps ensure that persons in need of a vaccine receive it and that adequately vaccinate increasing the risk for local adverse events (e.g., tetanus toxoid). Serologic test results for vaccine-preventable diseases (e.g., documented episodes of adverse events also should be recorded in the permanent medical record of the vaccine recipient.

Health-care providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the va of the person administering the vaccine. Additionally, the provider is required to record the edition date of the vaccine inform materials were provided. Regarding this Act, the term *health-care provider* is defined as any licensed health-care professiona public (including federal, state, and local departments and agencies), under whose authority a specified vaccine is administer be kept for all vaccines, not just for those required by the National Childhood Vaccine Injury Act.

Patients' Personal Records

Official immunization cards have been adopted by every state, territory, and the District of Columbia to encourage uniformit immunization status by schools and child care centers. The records also are key tools in immunization education programs ai of the need for vaccines. A permanent immunization record card should be established for each newborn infant and maintain these cards are distributed to new mothers before discharge from the hospital. Using immunization record cards for adolesce

Registries

Immunization registries are confidential, population-based, computerized information systems that collect vaccination data f geographic area. Registries are a critical tool that can increase and sustain increased vaccination coverage by consolidating v providers, generating reminder and recall vaccination notices for each child, and providing official vaccination forms and va operational immunization registry also can prevent duplicate vaccinations, limit missed appointments, reduce vaccine waste, locate immunization records or certificates. The National Vaccine Advisory Committee strongly encourages development of systems and recommends that vaccination providers participate in these registries whenever possible (*170*,*171*). A 95% parti operational population-based immunization registries is a national health objective for 2010 (*172*).

Reporting Adverse Events After Vaccination

Modern vaccines are safe and effective; however, adverse events have been reported after administration of all vaccines (*82*) reactions to extremely rare, severe, systemic illness (e.g., encephalopathy). Establishing evidence for cause-and-effect relatic alone is impossible because temporal association alone does not necessarily indicate causation. Unless the syndrome that occ pathologically distinctive, more detailed epidemiologic studies to compare the incidence of the event among vaccinees with t

often necessary. Reporting adverse events to public health authorities, including serious events, is a key stimulus to developi association with vaccination. More complete information regarding adverse reactions to a specific vaccine can be found in th a specific statement on vaccine adverse reactions (*82*).

The National Childhood Vaccine Injury Act requires health-care providers to report selected events occurring after vaccinati System (VAERS). Events for which reporting is required appear in the Vaccine Injury Table.¶ Persons other than health-car VAERS. Adverse events other than those that must be reported or that occur after administration of vaccines not covered by unusual, also should be reported to VAERS, even if the physician or other health-care provider is uncertain they are related c available in the FDA Drug Bulletin, by calling the 24-hour VAERS Hotline at 800-822-7967, or from the VAERS website at 2001).

Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act, is a no-faul suffered an injury or death as a result of administration of a covered vaccine can seek compensation. The program, which be as an alternative to civil litigation under the traditional tort system in that negligence need not be proven. Claims arising from through the program before civil litigation can be pursued.

The program relies on a Vaccine Injury Table listing the vaccines covered by the program as well as the injuries, disabilities, which compensation might be awarded. The table defines the time during which the first symptom or substantial aggravation Successful claimants receive a legal presumption of causation if a condition listed in the table is proven, thus avoiding the ne Claimants also can prevail for conditions not listed in the table if they prove causation. Injuries after administration of vaccin program are not eligible for compensation through the program. Additional information is available from the following:

National Vaccine Injury Compensation Program
Health Resources and Services Administration
Parklawn Building, Room 8-46
5600 Fishers Lane
Rockville, MD 20857
Telephone: 800-338-2382 (24-hour recording)
Internet: http:// www.hrsa.gov/bhpr/vicp (accessed November 7, 2001)

Persons wishing to file a claim for vaccine injury should call or write the following:

U.S. Court of Federal Claims
717 Madison Place, N.W.
Washington, D.C. 20005
Telephone: 202-219-9657

Benefit and Risk Communication

Parents, guardians, legal representatives, and adolescent and adult patients should be informed regarding the benefits and risk Opportunity for questions should be provided before each vaccination. Discussion of the benefits and risks of vaccination is

The National Childhood Vaccine Injury Act requires that vaccine information materials be developed for each vaccine cover *Information Statements*, must be provided by all public and private vaccination providers each time a vaccine is administered available from state health authorities responsible for immunization, or they can be obtained from CDC's National Immuniza (accessed November 7, 2001). Translations of Vaccine Information Statements into languages other than English are availab from the Immunization Action Coalition website at http://www.immunize.org (accessed November 7, 2001).

Health-care providers should anticipate that certain parents or patients will question the need for or safety of vaccination, refu vaccinations. A limited number of persons might have religious or personal objections to vaccinations. Others wish to enter i certain vaccines. Having a basic understanding of how patients view vaccine risk and developing effective approaches in dea is imperative for vaccination providers.

Each person understands and reacts to vaccine information on the basis of different factors, including prior experience, educa presentation, perceptions of the risk for disease, perceived ability to control those risks, and their risk preference. Increasingl sites, decisions regarding risk are based on inaccurate information. Only through direct dialogue with parents and by using a prevent acceptance of media reports and information from nonauthoritative Internet sites as scientific fact.

When a parent or patient initiates discussion regarding a vaccine controversy, the health-care professional should discuss the information, using language that is appropriate. Effective, empathetic vaccine risk communication is essential in responding recognizing that for certain persons, risk assessment and decision-making is difficult and confusing. Certain vaccines might b concerns should then be addressed in the context of this information, using the Vaccine Information Statements and offering available on the National Immunization Program website).

Although a limited number of providers might choose to exclude from their practice those patients who question or refuse va

strategy is to identify common ground and discuss measures that need to be followed if the patient's decision is to defer vacc
points regarding each vaccine, including safety, and emphasize risks encountered by unimmunized children. Parents should b
child care entry, which might require that unimmunized children stay home from school during outbreaks. Documentation of
including the refusal to receive certain vaccines (i.e., informed refusal), might reduce any potential liability if a vaccine-prev
patient.

Vaccination Programs

The best way to reduce vaccine-preventable diseases is to have a highly immune population. Universal vaccination is a critic
accomplished through routine and intensive vaccination programs implemented in physicians' offices and in public health cli
maintained in all communities to ensure vaccination of all children at the recommended age. In addition, appropriate vaccina
adults.

Physicians and other pediatric vaccination providers should adhere to the standards for child and adolescent immunization pr
vaccination practices for both the public and private sectors. The standards provide guidance on practices that will result in e
practices aimed at eliminating unnecessary prerequisites for receiving vaccinations, eliminating missed opportunities to vacc
needs, enhancing knowledge regarding vaccinations among parents and providers, and improving the management and repor
address the importance of recall and reminder systems and using assessments to monitor clinic or office vaccination coverag
Standards of practice also have been published to increase vaccination coverage among adults (*2*). Persons aged ≥65 years ar
them at risk for pneumococcal disease should receive ≥1 doses of pneumococcal polysaccharide vaccine. All persons aged ≥
increase the risk for complications from influenza should receive annual influenza vaccination. All adults should complete a
and receive a booster dose every 10 years. Adult vaccination programs also should provide MMR and varicella vaccines whe
mumps, rubella, or varicella. Persons born after 1956 who are attending college (or other posthigh school educational institut
place them at increased risk for measles transmission (e.g., health-care facilities), or who are traveling to areas with endemic
received two doses of MMR on or after their first birthday or other evidence of immunity (*6*,*173*). All other adults born after
MMR vaccine on or after their first birthday or have other evidence of immunity. No evidence indicates that administering M
reactions among persons who are already immune to measles, mumps, or rubella as a result of previous vaccination or diseas
encouraged for all persons who might be at increased risk (e.g., adolescents and adults who are either in a group at high risk
drug use, teenage pregnancy, or sexually transmitted disease).

Every visit to a physician or other health-care provider can be an opportunity to update a patient's immunization status with r
should take necessary steps, including developing and enforcing school immunization requirements, to ensure that students a
child care centers are protected against vaccine-preventable diseases. Agencies also should encourage institutions (e.g., hosp
policies regarding the appropriate vaccination of patients, residents, and employees (*173*).

Dates of vaccination (day, month, and year) should be recorded on institutional immunization records (e.g., those kept in sch
facilitate assessments that a primary vaccination series has been completed according to an appropriate schedule and that nee
appropriate time.

The independent, nonfederal Task Force on Community Preventive Services (the Task Force) gives public health decision-m
interventions to promote health and prevent disease, injury, disability, and premature death. The recommendations are based
regarding effectiveness and cost-effectiveness of these interventions. In addition, the Task Force identifies critical informatic
interventions, as well as the applicability to specific populations and settings and the potential barriers to implementation. Th
http://www.thecommunityguide.org (accessed November 7, 2001).

Beginning in 1996, the Task Force systematically reviewed published evidence on the effectiveness and cost-effectiveness o
coverage of vaccines recommended for routine use among children, adolescents, and adults. A total of 197 articles were iden
inclusion criteria, and were published during 1980--1997. Reviews of 17 specific interventions were published in 1999 (*174-*
Force made recommendations regarding the use of these interventions (*177*). A number of interventions were identified and
The interventions and the recommendations are summarized in this report (Table 7).

Vaccine Information Sources

In addition to these general recommendations, other sources are available that contain specific and updated vaccine informat

National Immunization Information Hotline

The National Immunization Information Hotline is supported by CDC's National Immunization Program and provides vaccin
the public, 8:00 am--11:00 pm, Monday--Friday:

Telephone (English): 800-232-2522
Telephone (Spanish): 800-232-0233
Telephone (TTY): 800-243-7889
Internet: http://www.ashastd.org (accessed November 7, 2001)

CDC's National Immunization Program

CDC's National Immunization Program website provides direct access to immunization recommendations of the Advisory C vaccination schedules, vaccine safety information, publications, provider education and training, and links to other immuniz http://www.cdc.gov/nip (accessed November 7, 2001).

Morbidity and Mortality Weekly Report

ACIP recommendations regarding vaccine use, statements of vaccine policy as they are developed, and reports of specific di *Morbidity and Mortality Weekly Report* (*MMWR*) series. Electronic subscriptions are free and available at http://www.cdc.g Printed subscriptions are available at

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402-9235

American Academy of Pediatrics (AAP)

Every 3 years, AAP issues the *Red Book: Report of the Committee on Infectious Diseases*, which contains a composite summ infectious diseases and immunizations for infants, children, and adolescents.

Telephone: 888-227-1770
Internet: http://www.aap.org (accessed November 7, 2001)

American Academy of Family Physicians (AAFP)

Information from the professional organization of family physicians is available at http://www.aafp.org (accessed November

Immunization Action Coalition

This source provides extensive free provider and patient information, including translations of Vaccine Information Statemer is http://www.immunize.org (accessed November 7, 2001).

National Network for Immunization Information

This information source is provided by the Infectious Diseases Society of America, Pediatric Infectious Diseases Society, A professional organizations. It provides objective, science-based information regarding vaccines for the public and providers. http://www.immunizationinfo.org (accessed November 7, 2001).

Vaccine Education Center

Located at the Children's Hospital of Philadelphia, this source provides patient and provider information. The Internet addres November 7, 2001).

Institute for Vaccine Safety

Located at Johns Hopkins University School of Public Health, this source provides information regarding vaccine safety con health-care providers and parents. It is available at http://www.vaccinesafety.edu (accessed November 7, 2001).

National Partnership for Immunization

This national organization encourages greater acceptance and use of vaccinations for all ages through partnerships with publi address is http://www.partnersforimmunization.org (accessed November 7, 2001).

State and Local Health Departments

State and local health departments provide technical advice through hotlines, electronic mail, and Internet sites, including pri immunization schedules, posters, and other educational materials.

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* During measles outbreaks, if cases are occurring among infants aged <12 months, measles vaccination of infants as young as 6 months can be undertaken as an outb months should not be counted as part of the series (**Source:** CDC. Measles, mumps, and rubella vaccine use and strategies for elimination of measles, rubella, and con of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1998;47[No. RR-8]:157).

† In certain situations, local or state requirements might mandate that doses of selected vaccines be administered on or after specific ages. For example, a school entry administered before the child's first birthday. ACIP recommends that physicians and other health-care providers comply with local or state vaccination requirements w

§ The exception is the two-dose hepatitis B vaccination series for adolescents aged 1115 years. Only Recombivax HB® (Merck Vaccine Division) should be used in th

¶ Internet sites with device listings are identified for information purposes only. CDC, the U.S. Public Health Service, and the Department of Health and Human Servic listed would all satisfy the needle-stick prevention regulations.

** Toxin neutralization testing is reliable but not readily available. Enzyme immunoassay tests are the most readily available, although passive hemagglutination is av performing the test for interpretive standards and limitations. Protective concentrations for diphtheria are defined as ≥0.1 IU/mL and for tetanus as ≥0.10.2 IU/mL.
†† As defined by a low age-specific total $CD4^+$ T lymphocyte count or a low $CD4^+$ T lymphocyte count as a percentage of total lymphocytes. ACIP recommendations f criteria for severe immunosuppression in persons with HIV infection (**Source:** CDC. Measles, mumps, and rubella vaccine use and strategies for elimination of measl mumps: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1998;47[No. RR-8]:157).
§§ As of January 2002, vaccines covered by the act include diphtheria, tetanus, pertussis, measles, mumps, rubella, poliovirus, hepatitis B, Hib, varicella, and pneumoc
¶¶ The Vaccine Injury Table can be obtained from the Vaccine Injury Compensation Program Internet site at <http://www.hrsa.dhhs.gov/bhpr/vicp/table.htm> (accesse
*** Standards for pediatric, adolescent, and adult immunization practices are being revised and will be posted on CDC's National Immunization Program Interne site the updates are available.

Abbreviations Used in This Publication

AAFP
: American Academy of Family Physicians

AAP
: American Academy of Pediatrics

ACIP
: Advisory Committee on Immunization Practices

DT
: pediatric diphtheria-tetanus toxoid

DTaP
: diphtheria and tetanus toxoids and acellular pertussis vaccine

DTP
: diphtheria and tetanus toxoids and whole-cell pertussis vaccine

EIA/ELISA
: enzyme immunoassay

FDA
: Food and Drug Administration

GBS
: Guillain-Barré syndrome

HBIG
: hepatitis B immune globulin

HbOC
: diphtheria CRM_{197} (CRM, cross-reactive material) protein conjugate

HBsAg
: hepatitis B surface antigen

Hib
: *Haemophilus influenzae* type b

HIV
: human immunodeficiency virus

HSCT
: hematopoietic stem cell transplant

IgG
: immunoglobulin G

IGIV
: intravenous immune globulin

IPV
: inactivated poliovirus vaccine

JIs
: jet injectors

MMR
: measles, mumps, rubella vaccine

OPV
: oral poliovirus vaccine

OSHA
: Occupational Safety and Health Administration

PCV
: pneumococcal conjugate vaccine

PPD
: purified protein derivative

PRP-OMP
: polyribosylribitol phosphate-meningococcal outer membrane protein

PRP-T
: PRP-tetanus

PPV
: pneumococcal polysaccharide vaccine

Td
: adult tetanus-diphtheria toxoid

VAERS
: Vaccine Adverse Event Reporting System

VAPP
: vaccine-associated paralytic polio

Definitions Used in This Report

Adverse event. An untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccinatio induced: caused by the intrinsic characteristic of the vaccine preparation and the individual response of the vaccinee; these e vaccination (e.g., vaccine-associated paralytic poliomyelitis); 2) vaccine-potentiated: would have occurred anyway, but were seizure in a predisposed child); 3) programmatic error: caused by technical errors in vaccine preparation, handling, or admini with vaccination by chance or caused by underlying illness. Special studies are needed to determine if an adverse event is a r Chen RT. Special methodological issues in pharmacoepidemiology studies of vaccine safety. In: Strom BL, ed. Pharmacoepi & Sons, 2000:707--32; and Fenichel GM, Lane DA, Livengood JR, Horwitz SJ, Menkes JH, Schwartz JF. Adverse events fo causation. Pediatr Neurol 1989;5:287--90).

Adverse reaction. An undesirable medical condition that has been demonstrated to be caused by a vaccine. Evidence for the randomized clinical trials, controlled epidemiologic studies, isolation of the vaccine strain from the pathogenic site, or recurr (i.e., rechallenge); synonyms include side effect and adverse effect).

Immunobiologic. Antigenic substances (e.g., vaccines and toxoids) or antibody-containing preparations (e.g., globulins and products are used for active or passive immunization or therapy. The following are examples of immunobiologics:

> **Vaccine.** A suspension of live (usually attenuated) or inactivated microorganisms (e.g., bacteria or viruses) or fracti immunity and prevent infectious disease or its sequelae. Some vaccines contain highly defined antigens (e.g., the pc type b or the surface antigen of hepatitis B); others have antigens that are complex or incompletely defined (e.g., kil attenuated viruses).
>
> **Toxoid.** A modified bacterial toxin that has been made nontoxic, but retains the ability to stimulate the formation of
>
> **Immune globulin.** A sterile solution containing antibodies, which are usually obtained from human blood. It is obta large pools of blood plasma and contains 15%--18% protein. Intended for intramuscular administration, immune glo maintenance of immunity among certain immunodeficient persons and for passive protection against measles and h
>
> **Intravenous immune globulin.** A product derived from blood plasma from a donor pool similar to the immune glo suitable for intravenous use. Intravenous immune globulin is used primarily for replacement therapy in primary anti of Kawasaki disease, immune thrombocytopenic purpura, hypogammaglobulinemia in chronic lymphocytic leukem immunodeficiency virus infection (Table 2).
>
> **Hyperimmune globulin (specific).** Special preparations obtained from blood plasma from donor pools preselected specific antigen (e.g., hepatitis B immune globulin, varicella-zoster immune globulin, rabies immune globulin, tetar globulin, cytomegalovirus immune globulin, respiratory syncytial virus immune globulin, botulism immune globuli
>
> **Monoclonal antibody.** An antibody product prepared from a single lymphocyte clone, which contains only antibod
>
> **Antitoxin.** A solution of antibodies against a toxin. Antitoxin can be derived from either human (e.g., tetanus antito (e.g., diphtheria and botulism antitoxin). Antitoxins are used to confer passive immunity and for treatment.

Vaccination and Immunization. The terms *vaccine* and *vaccination* are derived from *vacca*, the Latin term for cow. *Vaccin* material used (i.e., cowpox virus) to produce immunity to smallpox. The term *vaccination* was used by Louis Pasteur in the administering any vaccine or toxoid. *Immunization* is a more inclusive term, denoting the process of inducing or providing in Immunization can be active or passive. *Active immunization* is the production of antibody or other immune responses throug *immunization* means the provision of temporary immunity by the administration of preformed antibodies. Four types of imm immunization: 1) pooled human immune globulin or intravenous immune globulin, 2) hyperimmune globulin (specific) prep and 4) antitoxins from nonhuman sources. Although persons often use the terms *vaccination* and *immunization* interchangeal are not synonymous because the administration of an immunobiologic cannot be equated automatically with development of

Table 1

Morbidity and Mortality Weekly Report
Centers for Disease Control and Prevention
1600 Clifton Rd, MailStop E-90, Atlanta, GA 30333, U.S.A

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